

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 13, 2019

Jennifer DeCarlo Regulatory Specialist Reckitt Benckiser LLC. D/B/A Reckitt Benckiser Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054-0225

Subject: Label Amendment – Add Emerging Pathogen Language, Add Marketing Claims

and Update net contents

Product Name: Lysol Brand Disinfectant Bleach Plus

EPA Registration Number: 777-83 Application Date: May 11, 2017 Decision Number: 529814

# Dear Ms.DeCarlo:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance To Registrants: Process For Making Claims

Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), 
https://www.epa.gov/sites/production/files/201609/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are subject to the following additional terms of registration:

- 1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

- i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
  - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
  - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
  - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
- ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis\_2/public/wahid.php/Diseaseinformation/WI).
- b. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is [small non-enveloped, large non-enveloped, enveloped].
- c. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term B.3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term B.3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term B.3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.
- 5. Terms B.1 through B.4 above shall become immediately void and ineffective if registration for use against [identify label viruses] is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it

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bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Ben Chambliss by phone at (703) 308-8174, or via email at chambliss.ben@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P)

Office of Pesticide Programs

Enclosure: Efficacy Review

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## << FRONT PANEL >>

**ACTIVE INGREDIENT:** 

Sodium Hypochlorite..... 98.0% 

KEEP OUT OF REACH OF CHILDREN

WARNING: Eye and skin irritant. See (back) (side) panel for additional precautionary statements and first aid. Use only in well ventilated areas.

(NET CONTENTS): X FL. OZ. ((X PT.) (X QT.) (X FL. OZ.)) X (mL)

(L)

X x X FL. OZ. EACH: X FL. OZ. ((X PT.) (X QT.) (X FL. OZ.)) X TOTAL: X FL. OZ. ((X PT.) (X QT.) (X GAL.) (X FL. OZ.)) X

(mL) (L)

<< FRONT / BACK PANEL >>

EPA Reg. No.: 777-83

777-NJ-2 (Y) (YY) EPA Est. No.: 68777-NY-1 (Y) (YY) 75371-IN-1 (Y) (YY) 09019-OH-1 (Y) (YY) 09019-OH-2 (Y) (YY) 777-MO-001 (Y) (YY) 11525-IL-1 (Y) (YY) 312-WI-1 (Y) (YY) 55179-IN-1 (Y) (YY) 312-WI-3 (Y) (YY) 8155-OH-1 (Y) (YY)

777-PA-001 (Y) (YY) 475-PA-001 (Y) (YY) 71354-NC-1 (Y) (YY) 046813-CN-6 (Y) (YY)

475-MO-001 (Y) (YY)

(See bottom or side) (for Lot / Date code)

(Beginning of) (batch) (lot) code indicates EPA (Est.) (Establishment) (#) (No.) (Number)

See (batch) (lot) code for EPA (Est.) (Establishment) (#) (No.) (Number)

<< BACK PANEL >>

Questions? (Call:) (1-800-228-4722) (1-800-677-9218) (1-XXX-XXXX)

For ingredient (and other) information, (www.rbnainfo.com)

Distributed by: Reckitt Benckiser, Parsippany, NJ 07054(-xxxx)

Made in {insert country} © {year} RB

Contains no phosphates

This (bottle) (container) is made of 25% post-consumer recycled plastic.

Reckitt Benckiser HEALTH - HYGIENE - HOME

Company graphic logo

# << FRONT / BACK PANEL - Optional text >>

Recycle Symbol

Important facts (about this product)

Encourage your local authorities to establish a program to recycle this (bottle) (container).

IMPORTANT: For directions for use and first aid instructions in Spanish, please call 1-877-843-3817

Spanish Translation:

IMPORTANTE: Para instrucciones de uso y primeros auxilios en español por favor llame al 1-877-843-3817.

Learn more about (the importance of good hygiene habits) (and) (the appropriate use of disinfectants) (in good hygiene) (and the many ways that Lysol<sup>®</sup> is promoting good hygiene habits) (for your family and community) go to www.spreadinghealth.com

Bracketed information is denoted as: << directive >>, { insert as noted }, ( optional text ), [ required qualifier ]. The term "this product" used throughout this document may be replaced with the marketed product brand name. To use the term "germ\*\*" the product must be efficacious against 2 of the 3 major classes of organisms. The product label must identify the specific bacteria, virus, fungus & mold.

The term 'x' is a place holder for a number between 1 to 99.

The term "Y" is a place holder for a character A - Z.

ACCEPTED

02/13/2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

777-83

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<< NOTE: Any claim may appear on either FRONT / BACK panel in bullet / paragraph format – Unless otherwise noted. >>

<< INTRODUCTORY 6-mos. CLAIMS - will only appear on graphic label for the first 6 months product is on shelf >>

(New) (Improved) (Formula) (Scent) (Easy Grip Bottle) (New & Improved)

## << CROSS-PROMOTIONAL CLAIMS >>

Consumer: Only one coupon is redeemable per purchase and only on specified products and sizes. You pay any sales tax. May not be reproduced, purchased, traded or sold. Any other use constitutes fraud.

Expires xx/xx/xxxx

Like (insert Lysol brand name) (trigger) (cleaner)? Try (our) (insert Lysol brand name) (insert picture of Lysol wipes)

Like this fragrance? Try (our) other Lysol® products (insert picture of Lysol product)

Like this product? Try (our) other Lysol® products (insert picture of Lysol product)

Manufacturer's coupon

Retailer: You are authorized to act as our agent and redeem this coupon in acceptance with RB Coupon Redemption. Policy: face value plus 8¢. Send coupons to: Reckitt Benckiser, CMS Dept. #26600, 1 Fawcett Drive, Del Rio, TX 78840. Cash value 1/100 of 1¢. Good only in the U.S.A. Void where prohibited.

(Save (Now) XX(cent sign) (on) (any) (X) (Lysol) (Wipes) (insert brand name) (XX ct or higher))

Try (our) other Lysol® cleaning products (insert picture of Lysol product)

Try (our) other Lysol® fragrances (insert picture of Lysol product)

Try (our) Lysol® family of cleaning products (insert picture of Lysol product)

(Save) (\$) (X) (%) (Off) (free) (now) (up to) (on) (any) (X) (single packs of) (triple pack of) {insert Lysol brand name} (Lysol products) (X fl. oz. or larger size)

## << MARKETING CLAIMS >>

3X (the) Cleaning Power (on {insert soils – see Appendix 2})

(10) (Z) X CLEANING ACTIONS∞ <<where Z is a number between 1 and 50. For example 10X CLEANING ACTIONS∞>>

(x%) Better at (cutting) (removing) (eliminating) (tough) (kitchen) (grease) (soap scum)

(x%) Better than ever on (tough) grease (and) (soap scum)

X% more whitening power (per spray)

X% more shine (per spray)

(X-in-1) (3-in-1) (4-in-1) (4 Way) (Action) (5 in 1) (All-in-1) (Cleaning Power) (Mold & Mildew Remover) (with Bleach) (Multi-Action) (Multi-Clean) (Multi-Purpose) (Multi-Surface) (One-Step Cleaner Sanitizer1) (Power) (Power Foam) (Triple Action) (Cleaner) (With Bleach)

(Antibacterial) (Bactericidal\*) (Bactericide\*) (Cleaner) (Deodorizer) (Germicidal\*\*) (Virucidal†) (Fungicidal\*)

(Bathroom) (Floor) (Glass & Surface) (Kitchen) (Restroom) (Cleaner) (Deodorizer) (Deodorizes) (Disinfects) (Disinfectant) (Disinfecting) (Sanitizer) (Sanitizes) (Complete) (Easy) (Easy to use) (Effective) (Express) (Extreme) (Fast) (Quick & Easy) (Ready to Use) (Streak-free) (Streak-free formula) (Total) (Versatile) (Clean) (Cleaner) (Cleaning) (Degreaser) (Degreases)

(Beautiful) (Bright) (Brilliant) (Clean & Fresh) (Glistening) (See-through) (Streak-free) (Shine) (Cleans) (and) (Shines) (Grease releaser) (with Grease release action)

(Bonus x %) (Bonus x fl. oz.) (x fl. oz. at x fl. oz. Price) (x fl. oz. for the price of x fl. oz.) (x % discount) (x % more free)

(Bonus) (Economy) (Great) (Mega) (Super) (Trial) (Value) (Pack) (Refill) (Size) (Place 1 in each bathroom)

Brightens (and whitens in seconds) (as it cleans)

Cleans (better than ever) (with the power of bleach)

(Cleans) (Cuts through) (Eliminates) (Powers out) (Powers through) (Removes) (tough) (stubborn) (Bathroom) (Kitchen) (dirt) (grease) (grime) (soap scum) (soils) (stains) (and) (everyday messes) (with the power of bleach)

Cleans greasy dirt better than ordinary bleach alone

Complete Clean

Confidence of Lysol®

Contains a detergent cleaner plus chlorine bleach

Contains the most (effective) (fast-acting) grease cutters

Cuts tough grease

Cuts through (kitchen) (dirt), (grease and stains)

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Cuts through tough food stains and greasy soils on {insert use sites - see Appendix 2}

Deep Down Clean!

Developed for (food service<sup>2</sup>) (and) (general housekeeping)

Disinfects as it cleans1

(Dual)(Double) action

(Dual)(Double) action foamer

(Dual)(Double) action(:)(,) no scrubbing

(Dual) (Power) Cleaning

Easily removes tough (mold) (and) mildew) stains from sealed grout

Effective: Cleans, (Shines) (Disinfects) (and) (Deodorizes) washable (surfaces) ({insert surfaces – see Appendix 2}) (in)

({insert use sites - see Appendix 2})

Express Clean & Fresh

Extreme white clean

Fast acting brightener

Foaming Action

Foaming action: Less Scrubbing Foams for a (deep) (powerful) clean

For your (toughest) (hard to remove) stains

For use in {insert use sites - see Appendix 2}

Fresh Clean Scent

Great for everyday (cleaning), (deodorizing) (and) (disinfecting)

(Great) Whitening action

Great whitening power

Has a clean (fresh) (pleasant) scent

Immediate whitening action

(Intended) For use (only) (on) (in) {insert use sites / surfaces – see Appendix 2}

Leaves a (bright) (brilliant) (vibrant) shine

Leaves a sparkling shine

Lysol's best (ever) (grease) (and) (soap scum) (remover) (cleaner)

(Money back guarantee) (Your # 1 choice) (Take the Lysol® Challenge) (Try it yourself) (or) (Get your money back)

Multi (action) (purpose) (foamer) (trigger)

Multi Purpose Cleaner with Bleach (for Kitchens & Bathrooms) (for Kitchens & Restrooms) (for Kitchen(s) & Bath(s))

Nonabrasive formula (rinses away easily)

No scrubbing (required) (needed) (necessary)

Our best (cleaner) (soap scum) (remover) (cleaner) (cleaning power) (power cleaner)

Our best (kitchen) (grease) (and) (soap scum) (cutter) (remover) (ever)

Our shiniest cleaner

Our whitest shine

Penetrates x times (deeper)(faster)

Power of Bleach

Power of Lysol®

Powerful clean & shine

Powers out greasy dirt, mildew stains and tough food stains.

(Powers through) (cuts) (cleans) (tough) (household) (stains) (and) (disinfects)

Powers through (soap scum) (and) (grease) (better than ever)

Powers through (tough) (grease) (and) (soap scum) (better than ever)

Removes {insert soils – see Appendix 2} from {insert use sites – see Appendix 2}

Removes general soils, food stains, mold, mildew and soap scum.

Removes greasy dirt better than bleach alone

Removes mildew stains and soap scum

Removes mold and mildew stains

Removes soap scum

Removes (the toughest) (tough) stains

Removes tough {insert soils - see Appendix 2}

Removes tough: soap scum, bathtub rings, mildew (stains), hard water (stains)

Removes tough soils, food stains, mold, mildew and soap scum

Removes tough spots and stains

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Removes tough stains and soap scum

Scrub-Free shine

Shines and whitens in seconds

Sparkling white cleaning

Starts to whiten instantly

Starts to whiten on contact

(This product) cleans and disinfects kitchen (and) (bathroom) (restroom) surfaces, including {insert surfaces – see Appendix 2}

(This product) contains no phosphates and is germicidal when used as directed for disinfecting

(This product) has 3X Cleaning Power to remove {insert soils – see Appendix 2}

Use (this product) on {insert surfaces – see Appendix 2}

Use regularly for maximum home (maintenance) (cleanliness)

Whitening power

Whitening stain remover

Whitens & removes stains

Whitens X times more

Whitens and removes mold (stains) and mildew stains

Whitens and removes stains and greasy dirt

Whitens as it cleans

Whitens cutting surfaces and sealed grout in floors and walls

Whitens sealed grout in bathtubs, showers, floors and walls

Whitens to a (sparkling) shine

## << MARKETING CLAIMS - PROFESSIONAL >>

(This product) has been tested using the AOAC Use-Dilution Method For Commercial Use

## << FUNGISTATIC CLAIMS >>

Controls the growth of mold and mildew†††

(Even) removes x% of allergens††

Helps prevent the growth of mold and mildew+++

Prevents (and) (controls) mold & mildew growth for up to 7 days

Prevents the growth of mold and mildew†††

Prevents mold and mildew†††

(Reduces) (Removes) {insert allergens – see Appendix 2}

(Reduces) (Removes) (x% of) (the most) (common) (household) (allergens) (around your home) (around your kitchen)

(around your bathroom) (on your floors) ††

Removes (up to) (more than) (90%) (x%) of allergens††

# << SANITIZING CLAIMS - Hard, non-porous, non-food contact surfaces >>

Fast acting sanitizer

Kills bacteria on hard, non-porous surfaces in seconds\*\*\*

Kills (Eliminates) 99.9% of bacteria in 30 seconds\*\*\*

Kills (Eliminates) 99.9% of bacteria on hard, non-porous surfaces in 30 seconds\*\*\*

Sanitizes in 30 seconds: (Campylobacter jejuni) (Enterobacter aerogenes) (Escherichia coli O157:H7) (Listeria monocytogenes) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) (and) (Vibrio cholerae).

# << DISINFECTING CLAIMS - Hard, non-porous, non-food contact surface >>

Cleans, disinfects, whitens, deodorizes and eliminates odor-causing bacteria\*\*

Destroys mold and mildew

Disinfects, deodorizes and (kills) (eliminates) odor-causing bacteria\*\*

Disinfects with Bleach

Effective against: {insert organisms – see Appendix 1}

Effective against: organisms that can cause (the) common cold, infectious diarrhea, athlete's foot fungus, mold & mildew\*\*

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Even mold isn't too tough for Lysol®

Got Mold? (Kill) (Destroy) (Eliminate) (Wipe It Out) (Remove it) with Lysol®

Kills 99.9% of bacteria\*

Kills 99.9% of germs\*\*

Kills 99.9% of bacteria and viruses\*\*

Kills 99.9% of viruses and bacteria\*\*

Kills 99.9% of viruses†

Kills (99.9% of) (Clostridium difficile) (C difficile) (and) (Norovirus)

Kills bacteria\*

Kills (Campylobacter jejuni) (Staphylococcus aureus) (and) (&) (Aspergillus niger) ({insert organisms - see Appendix 1}) (in 5 minutes)

Kills Clostridium difficile in 5 minutes

(Kills) (Destroy) (Eliminate) (Wipes Out) (Removes) visible mold

(Kills) (Destroys) (Eliminates) (tough) (mold) (and) (mildew) without scrubbing

(Kills) (Destroys) (mold) (and) (mildew)

(Kills) (Eliminates) germs\*\*

(Kills) (Eliminates) (Removes) mold and mildew

Kills germs\*\*

Kills germs\*\* for a deep clean

Kills in 30 seconds {insert organisms with a 30 second contact time only from Appendix 1}}

Kills in 3 minutes {insert organisms- see Appendix 1}}

Kills in 5 minutes {insert organisms- see Appendix 1}}

Kills Norovirus in 30 seconds

Kills odor-causing bacteria

Kills Rhinovirus

(Kills) (Removes) (mold) (mildew)

Kills viruses†

Penetrates to (kill) (eliminate) and destroy tough mold, mildew and bacteria at its source

Bracketed information is denoted as: << directive >>, { insert as noted }, ( optional text ), [ required qualifier ]. The term "this product" used throughout this document may be replaced with the marketed product brand name. To use the term "germ\*\*" the product must be efficacious against 2 of the 3 major classes of organisms. The product label must identify the specific bacteria, virus, fungus & mold.

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## << USE DIRECTIONS >>

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

# **Apply Carefully - Contains Bleach**

Avoid contact with clothes, fabric, wood, rubber, carpet, painted / paper surfaces, non-porous vinyl surfaces, and finished floors. Rinse immediately after use on metal to avoid pitting or discoloration. Prolonged contact with metal, old porcelain, plastic laminate and marble may cause discoloration.

**To Operate:** Turn nozzle counter clockwise to preferred usage.

**To Operate:** Turn nozzle to ("ON") (desired) position.

(To Operate:) To Open: Lift tab up, push back and press tab down to lock into open position.

**To Close:** Release tab from locked position, push tab down and snap closed.

To Refill (Bottle): Remove trigger sprayer. Pour in product from refill container and replace trigger.

To Refill (Bottle): Remove trigger unit from empty bottle and attach to new bottle.

**To Clean (/ Deodorize) (/ Remove Allergens††):** (Spray) (Apply to) surface until thoroughly wet. Wipe with a clean cloth or sponge and then rinse.

To Clean (Lime Scale) (Soap Scum) (and) (Greasy Soil): Allow product to sit 15-20 seconds to penetrate soil before wiping clean. Repeat if necessary.

**To Sanitize / Disinfect:** Pre-clean surface. (Spray) (Apply to) surface until thoroughly wet. **To Sanitize:** Leave for 30 seconds before wiping. **To Disinfect:** Leave for 5 minutes before wiping.

(2) Rinse all food contact surfaces with water after use. If the vapors bother you, leave the room while the product is working.

**Kills Mold & Mildew:** Apply to pre-cleaned surface. Let surface remain wet for 5 minutes and then allow to air dry. Repeat application at weekly intervals or when mold and mildew growth appears.

To Clean No-wax Floors: Mix 1 cup [8 fl. oz.] of product per 1 gallon of water; mop until clean. Rinse for the best shine.

# << ADVISORY STATEMENTS >>

Can be used in cleaning tools that recommend the use of (this product). Do not use on eating/cooking utensils, glasses/dishes or cookware. Rinse bathtub / shower surfaces with water after using product.

If the last portion (of this product) is difficult to dispense, turn trigger 180° to face opposite direction; this will ensure full use of its contents.

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## << Additional USE DIRECTIONS (claim specific) - Specific to Commercial Branded products Only >>

# << TERMINAL STERILANT STATEMENT - qualified metal surfaces >>

This product is not for use on critical & semi-critical medical devices or medical equipment surfaces.

## << TERMINAL STERILANT STATEMENT – unqualified metal surfaces >>

This product is not to be used as a terminal sterilant / high level disinfectant on any surface that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body; or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enters normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

# << HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] >>

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids; and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 [associated with AIDS].

# SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES / OBJECTS **SOILED WITH BLOOD / BODY FLUIDS:**

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

**CONTACT TIME:** Allow surface / object to remain wet for 30 seconds.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

# << FOR COMMERCIAL LABELS WITH CLOSTRIDIUM DIFFICILE CLAIM >>

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST CLOSTRIDIUM DIFFICILE ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

**CLEANING PROCEDURE:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

INFECTIOUS MATERIALS DISPOSAL: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

The term 'x' is a place holder for a number between 1 to 99.

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## << PRECAUTIONARY / PHYSICAL-CHEMICAL HAZARD / FIRST AID / STORAGE & DISPOSAL >>

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

WARNING: Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Vapors may irritate. Use only in well-ventilated areas. Avoid prolonged breathing of vapors. Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease. Harmful if swallowed. For sensitive skin or prolonged use, wear rubber gloves. Wash after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

	FIRST AID
If in Eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a Poison Control Center or doctor for treatment advice.</li> </ul>
If on Skin or Clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a Poison Control Center or doctor for treatment advice.</li> </ul>
If Swallowed	<ul> <li>Call a Poison Control Center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the Poison Control Center or doctor.</li> <li>Do not give anything by mouth to an unconscious person</li> </ul>
If Inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>Call a Poison Control Center or doctor for further treatment advice.</li> </ul> CONTACT NUMBER
	omments or In case of an emergency call toll free (1-800-228-4722) (1-800-677-9218)(1-XXX-XXXX). uct container or label with you when calling a Poison Control Center or doctor, or going for treatment.

PHYSICAL AND CHEMICAL HAZARDS: This product contains bleach. Do not mix with other (household) chemicals such as products containing ammonia, toilet bowl cleaners or acid cleaners as hazardous gases may be released.

# << STORAGE & DISPOSAL - Residential containers >>

# << Trigger bottle >>

STORAGE AND DISPOSAL: Store in a cool, well-ventilated area, inaccessible to children. Keep securely closed. Refillable container. Do not reuse or refill except as described in the directions for use. Refill trigger bottle only with this product. If not refilling, discard in trash or offer for recycl(e)(ing), if available.

# << Pourable container >>

STORAGE AND DISPOSAL: Store in a cool, well-ventilated area, inaccessible to children. Keep securely closed. Non-refillable container. Do not reuse or refill this container. Discard in trash or offer for recycl(e)(ing),, if available.

## << STORAGE & DISPOSAL - Commercial / Institutional / Industrial containers >>

## **STORAGE AND DISPOSAL:**

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a cool, well-ventilated area, inaccessible to children. Keep securely closed. PESTICIDE DISPOSAL: To avoid waste, use all material in this container according to label directions. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse (or equivalent). Follow pesticide disposal instructions for rinsate. Then discard in trash or offer for recycl(e)(ing),, if available.

Bracketed information is denoted as: << directive >>, { insert as noted }, ( optional text ), [ required qualifier ].

The term "this product" used throughout this document may be replaced with the marketed product brand name.

To use the term "germ\*\*" the product must be efficacious against 2 of the 3 major classes of organisms. The product label must identify the specific bacteria, virus, fungus & mold.

The term 'x' is a place holder for a number between 1 to 99.

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# << Optional Graphic Icons >>









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## <<APPENDIX 1>>

# << SUPPORTING CLAIM QUALIFIERS – must appear before 'Directions For Use' on Back Panel label >>

- (Destroys Mold & Mildew), (Removes Soap Scum), (Deep Clean), (Whitens), (Brightens), (Foaming Action), (Bleach Scent), (Greasy Soil Removal), (Targeted Spray), (Versatile)
- when used according to disinfection instructions
- (2) Rinse all food contact surfaces with water after use. If the vapors bother you, leave the room while the product is working.

## << SUPPORTING ALLERGEN REMOVAL CLAIM QUALIFIER >>

- †† This product removes the following allergens: (cat dander) (cockroach debris) (cockroach matter) (cockroach particles) (dog dander) (dust mite debris) (dust mite matter) (dust mite particles) (hair) (pet dander) (pet hair) (pollen particles).
- ††† Prevents and controls mold & mildew growth for up to 7 days

## << SUPPORTING SANITIZING CLAIM QUALIFIER >>

\*\*\* Kills 99.9% of (Campylobacter jejuni) (Enterobacter aerogenes) (Escherichia coli O157:H7) (Listeria monocytogenes) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) (and) (Vibrio cholerae) on hard, non-porous surfaces in 30 seconds.

# << SUPPORTING DISINFECTING CLAIM QUALIFIERS >>

- \* Kills (Aspergillus niger) (Campylobacter jejuni) (C difficile) (Enterococcus faecalis) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) and (Trichophyton mentagrophytes) (on hard non-porous surfaces) (in 5 minutes).
- \*\* Kills 99.9% (of) (Campylobacter jejuni) (C difficile)(Enterococcus faecalis) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) (Herpes Simplex Virus Type 1 & 2) (Human Immunodeficiency Virus Type 1) (Rhinovirus Type 39) (Rotavirus WA) (and) (Respiratory Syncytial Virus) (on hard non-porous surfaces) (in 5 minutes).
- † Kills (Herpes Simplex Virus Type 1 & 2) (Human Immunodeficiency Virus Type 1) (Rhinovirus Type 39) (Rotavirus WA) (and) (Respiratory Syncytial Virus) (on hard, non-porous surfaces) (in 5 minutes).

Symbol Designation – used on product labels			
Single asterisk (*) Dagger (†) Double asterisk (**) Triple asterisk (***) Double dagger (††)	Bacteria * / Fungi Viruses † Germs ** Sanitizes *** Allergens ††	Used for identifying disinfection against specific bacteria or fungi Used for identifying disinfection against specific viruses Used for identifying disinfection against specific bacteria & viruses / fungi Used for identifying sanitization against bacteria Used for identifying the removal of specific non-living allergens	

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# This product has been tested and found effective against the following micro-organisms:

Bacteria & Virus << Disinfection - Hard, non-porous surfaces >>				
Bacteria (5 minutes)	(ATCC No.)	Viruses (5 minutes)	(ATCC No.)	
Enterococcus faecalis	(838)	Herpes Simplex Virus Type 1	(VR-733)	
Pseudomonas aeruginosa	(15442)	Herpes Simplex Virus Type 2	(VR-734)	
Salmonella enterica	(10708)	Human Immunodeficiency Virus Type 1	n/a	
Staphylococcus aureus	(6538)	Rhinovirus Type 39 (common cold)	(VR-340)	
Clostridium difficile (C Difficile)	(43598)	Rotavirus WA (infectious diarrhea)	(VR-2018)	
		Respiratory Syncytial Virus[RSV]	(VR-26)	
Bacteria (3 minutes)	(ATCC No.)	Viruses (30 seconds)	(ATCC No.)	
Campylobacter jejuni	(29428)	Human Immunodeficiency Virus Type 1	n/a	
17		Rhinovirus Type 39 (common cold)	(VR-340)	
		Rotavirus WA (infectious diarrhea)	(VR-2018)	
		Norovirus		
		Duck Hepatitis B Virus (DHBV)		
<< Fungicidal – Hard, non-porc	ous surfaces >>	<< Mildew Fungistat – Hard, non-poro	us surfaces >>	
Fungi (5 minutes)	(ATCC No.)	Fungi (3 minutes)	(ATCC No.)	
Aspergillus niger	(6275)	Aspergillus niger	(16404)	
Trichophyton mentagrophytes	(9533)			
<< Sanitization	on – Hard, non-porous	, non-food contact surfaces >>	I	
Bacteria (30-seconds)		(ATCC No.)		
Campylobacter jejuni		(29428)		
Enterobacter aerogenes		(13048)		
Escherichia coli O157:H7		(43888)		
Listeria monocytogenes		(19111)		
Pseudomonas aeruginosa		(15442)		
Salmonella enterica		(10708)		
Staphylococcus aureus		(6538)		
Vibrio cholerae		(11623)		

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# <<APPENDIX 2>>

# << SOILS / ODORS / SURFACES / USE SITES - May be listed on product label in the singular or plural form >>

# Soils: (Graphic - depicting soil)

Food stains	Grime	Mildew stains	Soap scum
General soils	(Grease) (Greasy) (soils)	Mold stains	Tough soils
Bathtub rings			

# Non-living Allergens:

Cat dander	Dog dander	Hair
Cockroach debris	Dust mite debris	Pet dander
Cockroach matter	Dust mite matter	Pet hair
Cockroach particles	Dust mite particles	Pollen particles

# Hard Non-porous Surfaces: (Graphic - depicting surface)

Appliance exterior	Food Carts	Refrigerator / Freezer exterior
Cabinet (non-wood)	Garbage (Can)(Pail)(Container)	Shower (Shower Stall)
Counter (Countertop)	Glazed Ceramic Tile	Sink
Faucet	Glazed Porcelain Surface	Stove (Stovetop)
Fiberglass Fixtures	Sealed Grout	Toilet exterior
Fixtures (Chrome / Stainless Steel)	Highchair (non-wood)	(Tub) (Bathtub)
Floors (No-wax)	Kitchen Table	(Glazed Tiled) Wall
Floors (Sealed Ceramic Tile)	Microwave exterior	Vinyl Shower Curtain
Floors (Vinyl)	Non-medical (Chrome / Stainless Steel)	Water Fountain

# Household Use Sites: (Graphic - depicting site)

Bathroom	Family Room	^ Kitchen	Nursery
Bedroom	Garage	Laundry Room	Play Room
Den / Study	Home / House	Living Room	Storage area / room
^ Dining Room			
^ This product is not approved for use on food-contact surfaces.			

# Commercial Use Sites: (Graphic - depicting site)

^ Cafeteria	Health Care Facility	Nursing Home	Restroom
Day Care Center	Hospital	Office Building	School
Dental Office	Hotel / Motel	Physicians Office	^ Food Service Areas
Doctor's Office	Infirmary	^ Restaurant	
^ This product is not approved for use on food-contact surfaces.			

NOTE: Bracketed information is denoted as: << directive >>, { insert as noted }, ( optional text ), [ required qualifier ]. The term "this product" used throughout this document may be replaced with the marketed product brand name. To use the term "germ\*\*" the product must be efficacious against 2 of the 3 major classes of organisms. The product label must identify the specific bacteria, virus, fungus & mold.

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## <<APPENDIX 3>>

## << EMERGING VIRAL PATHOGENS CLAIMS >>

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	Rhinovirus Type 39 Norovirus
Large, non-enveloped virus	Rhinovirus Type 39 Norovirus
Small, non-enveloped virus	Rhinovirus Type 39 Norovirus

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information."